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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,657	03/03/2006	Robert M. Jones	34.US5.PCT	4098
26204	7590	12/17/2009		
FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MURRAY, JEFFREY H	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			12/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/541,657	Applicant(s) JONES ET AL.	
	Examiner JEFFREY H. MURRAY	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 12-14, 16-66, 73, 74, 78-85, 87-92 and 100 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 62-66, 79-85, 87-92 and 100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-14, 16-61, 73, 74 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to a petition decision granted on December 3, 2009. The petition was granted in part. Therefore the examiner no longer is requiring applicants to provide an election of species as part of the restriction requirement. In addition, the claim objection for non-elected subject matter in claims 1-78 is also withdrawn. Examiner still considers the claims as presented in the amendment filed on June 9, 2009 to lack unity of invention. The amendments which narrow the claims and withdraw non-elected inventions, are not consonant with the applicant's elected group. Applicants have narrowed the V, W, X and Y variables appropriately. However the remaining variables do not permit the compound to have unity of invention. Examiner will continue to examine the claims in light of the elected Group V. There are seventy-six claims pending and sixty claims under consideration. Claims 1-3, 12-14, 16-61, 73, 74 and 78 are pending. Claims 6-11, 15, 67-72, 75-77, 86 and 93-99 have been withdrawn. Claims 4, 5, 63-66, 79-85, 87-92 and 100 have been cancelled. This is the second action on the merits.

Withdrawn Rejections/Objections

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Drawings

The corrected drawing was received on June 9, 2009. This drawing is accepted.

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Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 12-14, 16-61, 73, 74 and 78 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pyrimidine where the N-A-B-D ring is a piperidinyI or piperazinyl; and Ar₁ is a phenyl or fused phenyl ring, does not reasonably provide enablement for all of the other groups listed nor any hydrates or solvates within the broad Claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants have argued first that the examiner misidentified the structures as “triazolopyrimidines and pyrazolopyrimidines” instead of just pyrimidines. Applicants are correct and this typographical error has been corrected.

Second, applicants have argued that solvates and hydrates have been reasonably enabled, examiner disagrees. Vippagunta, et. al. does explain that solvates and hydrates do exist, yes, and goes on to state that as many as 1/3 of all pharmaceuticals MAY form hydrates or solvates. However, the applicants have not shown in any reasonable way that they have enabled compounds to form solvates or hydrates, they merely believe that some of them will form arguing probability. Applicants have not pinpointed which compounds will form a solvate, which will form a hydrate, which may form both and which will form neither. They merely speculate that

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because there is a chance of formation, that this must be good enough. Applicants must teach the current invention limitation of solvates and hydrates, which they do not. Vippagunta states that the formation of solvates and hydrates is unpredictable, therefore merely stating that exposing a compound to water or a solvent will generate the hydrate or solvate is completely false, as stated prior, 2/3 of all pharmaceuticals will NOT form the hydrate or solvate. No new matter permitted. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 1-3, 12-14, 16-61, 73, 74 and 78 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The identity of “heteroaryl” and “heterocyclic” moieties still requires clarification. Applicants' are correct in noting examiner made a typographical error in using the term “heterocycloalkyl” and not “heterocyclic”.

The terms are defined vaguely with non-limiting examples making them impossible to determine. For example, when one states, “heterocyclic” and then provides a list of well over 30 examples and states the list is “non-limiting”, how can this be considered definite? One skilled in the art could instantly envision well over one hundred ring systems that qualify under this vague definition. Does the applicant wish to claim a thiophene, triazolopyrimidine or a [1,2]oxazino[6,5,4-de][2,6]naphthyridine? If the ring desired is a pyridine ring, is it 2-pyridyl, 3-pyridyl, or 4-pyridyl ring? Applicant must narrow such broad terminology by either eliminating such a vague definition or by

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inserting the specific ring systems they wish to cover into the claim themselves.

Applicants are invited to contact examiner if they have further questions regarding this issue. No new matter. Appropriate correction required.

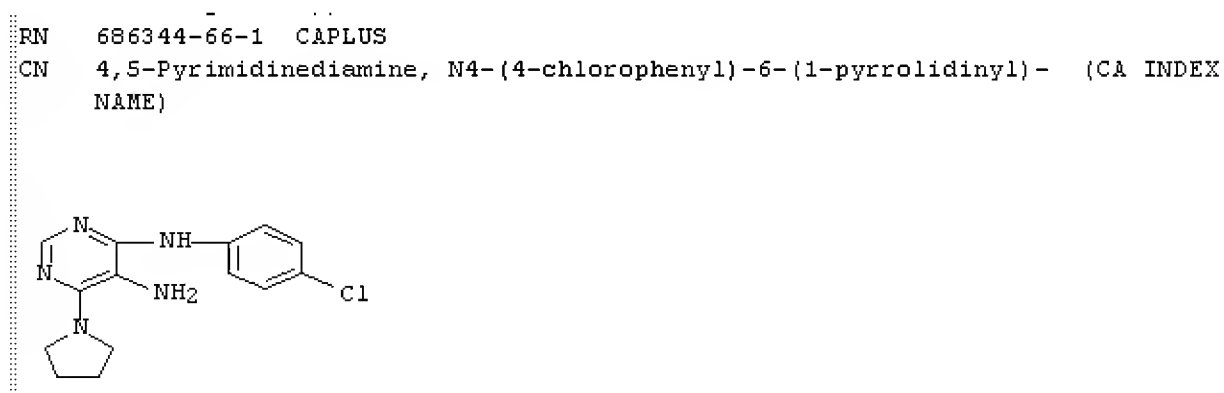
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 16 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffith, et. al., WO 2004037823. The reference teaches the following compound as example I-(17A-1)a on page 84 of the specification:



Whereby X and Y are N; W is a NH; V is absent; Ar₁ is a 4-chlorophenyl ring; R₁ is hydrogen; Z is an amino group; and the N-A-B-D ring is a pyrrolidinyl ring.

Conclusion

Claims 1-3, 12-14, 16-61, 73, 74 and 78 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner , Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**